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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/077,194
Filing Date: December 04, 1998
Appellant(s): BOHN ET AL.

Maryann Puglielli
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/21/07 appealing from the Office action mailed 1/25/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal: Appeal No. 2004-0309 and ongoing appeal for related application 10/606,229 (appeal number has not yet been assigned).

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claim Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,514,490	Odds	02-2003
4,185,106	Dittmar	01-1980

Dascalu et al. WO 06/29045 (09-1996).

Lange WO 88/00041 (01-1988).

Sanfilippo et al. "An Overview of Medicated Shampoos Used in Dandruff Treatment" P&T, vol. 31, no. 7, (2006), pages 396-400.

International Eczeme-Psoriasis Foundation. "Actively helping Eczema & Psoriasis Sufferers" Retrieved from http://www.internationaleczema-psoriasisfoundation.org/seborrheic_dermatitis.php4 (July 8, 2007), pages 1-4.

Janniger et al., "Seborrheic Dermatitis" American Family Physician, (July 1995), pages 149-155.

WebMD, "Dandruff Warning Signs, Symptoms, and Treatment on MedicineNet.com" Retrieved from http://www.medicinenet.com/seborrhea/article.htm (July 8, 2007), pages 1 of 3.

Lagarde WO 96/02226 (02-1996).

Wikipedia, "Category: Surfactants" Retieved from http://en.wikipedia.org/wiki/Category:Surfactants (12/3/05), page 1.

Green People, "Sodium Laurel Sulphate" Retrieved from http://www.greenpeople.co.uk/Organics_Features_SLS.htm (12/3/05), page 1.

Avre Skin Care, "Dermatology Dictionary" Retrieved from http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html (12/3/05), pages 1 and 10.

FDA, "Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis" 56 FR 63568 (December 4, 1991), pages 1-3.

Dreumex, "Dreumex Liquid Soaps" Retrieved from http://www.signus.com/dsoftsoap.htm (12/3/05), page 1.

Brinkster, "The pH Scale" Retrieved from http://misterguch.brinkster.net/acidtutorial.html (12/3/05), page 1.

Verdicchio et al. EP 0117135 A2 (08-1984).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims Rejections - 35 U.S.C. 112, first paragraph

Claims 38, 40, 41, 42, 48 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Claims 38 was amended in 2/22/05 response to recite "… administering to the patient an amount effective for the treatment of seborrheic dermatitis of a

composition comprising: (A) a sole active component consisting of at least one 1-hydroxyl-2-pyridone of formula I … in free form or as a pharmaceutically acceptable salt … wherein the composition has a pH ranging from about 4.5 to about 6.4" in lines 3-5 and the last line of the claim. However, the Examiner cannot find support for this claim limitation with regard to the "pharmaceutically acceptable salt" embodiment. For example, Appellants' specification states, "… when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids" (e.g., see specification, page 8, lines 30-32; see also Example 7 wherein "lactic acid" is used to adjust the pH). Furthermore, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "… acids per se possess an antimicrobial action, such as fumaric acid and azelaic acid. In this way the effect of the antimycotic in phase I as well as phase II is enhanced!"; see also paragraph bridging pages 9-10, "Examples of these acids are … lactic"). Appellants have not shown where support for this new genus of compounds that contains "1-hydroxyl-2-pyridone of formula I salt + "non-active" organic acids" can be found. If Appellant believes this rejection is in error, Appellant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02. Therefore, claim 38 and all dependent claims represent new matter.

Claims Rejections - 35 U.S.C. 112, second paragraph

Claims 38-42, 48 and 61-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

A. For **claim 38**, the "pharmaceutically acceptable salt" embodiment requires two active ingredients, (1) the salt of a compound of formula I and (2) the organic acid that is used to adjust the pH (e.g., see specification, page 8, lines 30-32, "… when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids"; see also Example 7 wherein "lactic acid" is used to adjust the pH; see especially dependent claim 65 wherein "lactic acid" is specifically required by the claims, which further limits independent claim 38) and, as a result, the claim cannot be limited to a "sole" active ingredient. For example, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "… acids per se possess an antimicrobial action"; see also paragraph bridging pages 9-10, "Examples of these acids are … lactic"; see especially, page 15, second set of ingredients, "lactic acid … (bacterio and mycostatic agent)"). Thus, it is not clear how the composition comprises a "sole" active ingredients when more than one active ingredients are being claimed (e.g., formula I salt + lactic acid). Consequently, the metes and bound of the claimed invention cannot be determined. Therefore, claim 38 and all dependent claims are rejected under 35

U.S.C. 112, second paragraph.

B. For **claims 38-42, 48, 53, 55-59, 61-67**, the term "seborrheic dermatitis" is vague and indefinite in view of the prosecution history. For example, Appellants state, "Dascalu et al. misuses dermatology nomenclature by confusing 'dandruff' with 'seborrheic dermatitis' … Although seborrheic dermatitis involving the scalp may give rise to a mistaken diagnosis of dandruff, it is well understood in the field of dermatology that seborrheic dermatitis is a condition distinct from dandruff" (e.g., see 4/24/02 response, pages 19-20). Appellants define "seborrheic dermatitis" as "a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites" (e.g., see specification, page 1). Appellants further state, "Pityrosporum … is assumed to be the cause of seborrheic dermatitis" (e.g., see specification, page 1, last paragraph). However, Dascalu et al. disclose a treatment for the exact same symptoms as those defined in Appellants' specification (e.g., see Dascalu et al., line 12 wherein inflammation is disclosed; see also page 5, Table 1, patient 5, wherein a high degree of scaling is disclosed; see also page 5, Table 1, patient 2 wherein a high degree of "itching" is disclosed; see also Table 5, patient 5 wherein the overall severity of the dandruff is characterized as "severe" or, in Appellants' words, not just "simple dandruff"). In addition, Dascalu et al. explicitly state that their treatment inhibits

the exact yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Appellants are relying on to make this distinction (i.e., there is no basis for this assertion). Thus, the metes and bound of the claimed invention cannot be determined. Therefore, claims 38-42, 48, 53, 55-59, 61-67 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102 (Lagarde)

Claims 39 and 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lagarde (WO 96/02226) (Date of patent is **February 1, 1996**) (translation provided) as evidenced by Wikipedia (e.g., Wikipedia, "Category: Surfactants" last modified 24 November 2005, page 1, accessed on 12/3/05 at http://en.wikipedia.org/wiki/Category:Surfactants).

For ***claims 39, 62 and 63***, Lagarde et al. (see entire document) disclose a novel combination product comprising an anti-fungal agent selected from the 1-hydroxyl-2-pyridones such as circlpirox or octopirox and, secondly, crotamiton as an antifungal agent activity enhancer (e.g., see Lagarde et al., abstract), which anticipates the claimed invention. For example, Lagarde et al. discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said combination (e.g., see page 5, middle paragraph, "Moreover, seborrheic dermatitis is more common in patients that have atopical background, cervico-cephalic atopical dermatitis, with the presence of

orbicular anti-pitysrosporum specific Ig E in which the rate is highly correlated with the severity of the disease. With respect to dermatophytoses we can mention athlete's foot, scalp disease as well as all cases of onychomycosis. Given all of these pathologies, few therapies are actually effective"; see also page 6, paragraphs 3 and 4, "Therefore there is a real need for an anti-fungal product that would have different qualities … the present invention deals with a new combination product, in which the synergistic combination offers improved anti-fungal activity"). In addition, Lagarde et al. discloses at least one 1-hydroxyl-2-pyridone of formula I as the sole active component (e.g., page 7 of the translation formula (I); see especially see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed). Furthermore, Lagarde et al. discloses, for example, the use of a surfactant (e.g., see page 16 of the translation, last paragraph, "It is quite evident that these formulas are not limiting and that it is important to make certain of the compatibility of surface-active agents with the combination 1-hydroxy-2-pyridone /crotamiton according to the invention; see also Examples wherein surfactants like Cocamide DEA, Cocamide MEA, Cocamidopropyl betaine are disclosed). Lagarde et al. do not state that Cocamide DEA (non-ionic), Cocamide MEA (non-ionic), Cocamidopropyl betaine (amphoteric) are "surfactants", but the Examiner contends that these would be inherent properties of these molecules as exemplified by Wikipedia (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant … which is included as a foaming agent … in a huge variety of commonly

used products … shampoos").

For ***claim 61***, Lagarde et al. disclose the cyclohexyl R4 group (e.g., see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed).

For ***claim 64***, Lagarde et al. discloses at least one "additional" surfactant such as cocamidopropyl betaine + Cocamide MEA. (e.g., see Example 4).

Claims Rejections - 35 U.S.C. 102 (Lange)

Claims 39 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange (WO 88/00041) (Date of Patent is **14 January 1988**) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html).

For ***claims 39, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic dermatitis"; see

also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** … In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Appellants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having

1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same phase I composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant … which is included as a foaming agent … in a huge variety of commonly used products … shampoos").

For ***claim 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

Claim Rejections - 35 USC § 103 (Lange)

Claims 38-42, 48, 53-58, and 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange (WO 88/00041) (Date of Patent is **14 January 1988**) and FDA (Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis. 56 FR 63568, December 4, 1991, pages 1-3) and Dascalu et al. (WO 96/29045) (Date of

Patent is **September 26, 1996**) (of record) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html) and Dreumex (Dreumex, "Dreumex Liquid Soaps", no date, page 1, accessed on 12/3/05 at http://www.signus.com/dsoftsoap.htm) and Odds et al. (U.S. Patent No. 6,514,490) (Date of patent is **February 4, 2003**) and Brinkster (Brinkster, "The pH Scale", page 1, no date, accessed 12/3/05 at http://misterguch.brinkster.net/acidtutorial.html).

For ***claims 39, 41, 42, 56, 57, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic dermatitis"; see also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** … In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-

(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Appellants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium

laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant … which is included as a foaming agent … in a huge variety of commonly used products … shampoos").

For ***claims 48, 58 and 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

The prior art teaching of Lange differ from the claimed invention as follows:

For ***claims 38, 53, 65 and 66***, Lange fails to recite the use of a pH range between about 4.5 to about 6.5. Lange only teaches a "neutral" pH (e.g., see Lange, page 6, last paragraph). Although Lange does not define the term "neutral" in terms of a numeric range, the Examiner contends that a pH range between 6-8 is generally considered to be neutral for shampoo products (e.g., see Dreumex, page 1, "Dreumex has developed three types of liquid soaps: Each has a (neutral) pH-value of 6-7; see also Odds et al., column 5, last paragraph "Some of the first active ingredients when at approximately neutral pH (pH 6 to 8)"; see also Brinkster, "Solutions with a pH between 6 and 8 are usually referred to as 'neutral' by nonscientists"). Thus, Lange teaches a pH range that

overlaps in scope with the present invention (i.e., pH 6-8 overlaps in scope with a pH of about 4.5 to about 6.5). In addition, Lange teach that lowering the pH to 4-5, using organic acids like lactic acid, do not adversely affect the anti-mycotic action of the 1-hydroxyl-2-pyridones like pirocton olamine (e.g., see page 10, paragraph 2) and provide favorable bacterio and mycostatic properties on their own (e.g., see Lange, page 15, bottom).

For ***claims 40, 55 and 61***, the combined references of Lange and FDA fail to teach the use of a cyclohexyl radical.

For ***claims 53 and 54***, Lange fails to recite the use of a keratolytic agent.

However, FDA teach the following limitations that are deficient in Lange:

For ***claims 38, 53, 65 and 66***, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. cir. 1990). Here, the pH range disclosed by Lange (pH 6-8 for neutral solutions) overlaps with the claimed about 4.5 to about 6.5 range disclosed by Appellant and, as a result, a prima facie case of obviousness has been set forth in accordance with *In re Wertheim* and *In re Woodruff*. Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties

(e.g., see *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). Here, Lange teaches that a pH range of 4-6 can be used in the "phase II" solution (e.g., see page 10, paragraph 2), which indicates that pirocton olamine (which is used in both "phase I" and "phase II") would continue to function as anti-mycotic even at this lower pH range. Thus, a person of skill in the art would expect pirocton olamine to have the same anti-mycotic properties whether it was at a neutral pH (6-8) or a more acidic pH (4-5). In addition, a person of ordinary skill in the art would have been motivated to adjust the pH to 4-5 using lactic acid because of its favorable bacterio and mycostatic properties (e.g., see Lange, page 15, bottom of page).

For ***claims 40, 55 and 61***, Dascalu et al. (see entire document) teach the use of use of a cyclohexyl radical in the R^4 position (e.g., see claim 4; see also page 3, last paragraph).

For ***claims 53 and 54,*** FDA (see entire document) teaches the use of keratolytic agents like salicylic acid are suitable for topical application in the treatment of seborrheic dermatitis (e.g., see FDA, page 1, Sec. 358.701, page 2,

Sec. 358.710, part (b)-(b)(4), "Active ingredients for the control of seborrheic dermatitis … Salicylic acid, 1.8 to 3 percent").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use keratolytic agents like salicylic acid in the medicinal treatment shampoo because the FDA explicitly approved this ingredient for its use in treating dandruff and seborrheic dermatitis. Furthermore, one of ordinary skill in the art would have been motivated to use "salicylic acid" as taught by the FDA with the medicinal treatment shampoo as taught by Lange because the FDA states that active ingredients like salicylic acid are "recognized as safe and effective" for treating seborrheic acid. Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because the FDA approved the use keratolytic agents like salicylic acid for the treatment of dandruff and seborrheic dermatitis and also shows its use in conjunction with pyrithion zinc, which is explicitly disclosed as a preferred embodiment of Lange (e.g., see Lange, Example 2; see also abstract). In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to made to use ciclopiroxolamine in the seborrheic dermatitis treatment described by the combined references of Lange and FDA because Dascalu et al. explicitly states that ciclopiroxolamine is useful for this purpose (e.g., see claims 1 and 4, "A composition for treatment of seborrheic dermatitis of the scalp …

consisting of … ciclopiroxolamines"). Furthermore, one of ordinary skill in the art would have been motivated to use ciclopiroxolamines as taught by Dascalu et al. because Dascalu et al. teach that these compounds are a "preferred' embodiment (e.g., see claim 4) . Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Dascalu et al. teach several successful examples of using anti-fungal agents like ciclopiroxolamines (e.g., see claims and examples) and, in addition, it is

structurally related to the anti-fungal agents disclosed by the combined references of Lange and the FDA (e.g., 1-hydroxyl-2-pyridones are disclosed in each case).

Claims Rejections – 35 U.S.C. 102/103 (Verdicchio et al.)

Claims 38-42, 48 and 61-66 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Verdicchio et al. (EP0117135 A2) (Published August 19, 1984) in view of Janniger et al. (Janniger et al. "Seborrheic Dermatitis" *American Family Physician*, **July 1995**, page 149-155) and Dittmar (U.S. Patent No. 4,185,106) (Date of Patent is January 22, 1980) (of record, e.g., see 6/16/1999 FAOM, withdrawn apparently because the Dittmar reference alone did not teach the claimed pH values). Please note that a 102/103 rejection may is appropriate when the interpretation of the claim(s) is or may be in dispute, i.e., given

one interpretation, a rejection under 35 U.S.C. 102 is appro-priate and given another interpretation, a rejection under 35 U.S.C. 103(a) is appropriate. See section MPEP § 706.02(m). Here the term "seborrheic dermatitis" is in dispute (see 35 U.S.C. § 112, second paragraph rejection above).

For ***claims 38 and 39***, Verdicchio et al. (see entire document) disclose a composition for treating dandruff in a human patient (e.g., see abstract and introduction; see also bottom of page 20, "Two groups of 8 people each who have dandruff are compared using each test shampoo twice weekly"). Verdicchio et al. do not explicitly state that these people have seborrheic dermatitis, but the Examiner contends that this is inherently disclosed because dandruff is a form of Seborrheic Dermatitis according to Janniger et al. (e.g., see Janniger et al., abstract, "Seborrheic dermatitis is a common condition that usually appears as simple dandruff."; see also page 149, paragraph 1, "In adolescents and adults, seborrheic dermatitis commonly is manifested as 'dandruff'"). Verdicchio et al. also disclose administering a composition comprises a sole active component which is hydroxy pyridone such as Octopirox. Octopirox falls within the scope of Appellants' formula (I) when R^4 = 2,4,4-trimethylpentyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H (e.g., see page 12, lines 31-34 disclosing the use of octopirox as recited in U.S. Patent No. 4,185,106; see also U.S. Patent No. 4,185,106, claim 3 wherein ethanolamine

salt of 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridone (i.e., octopirox) is set forth. Verdicchio et al. also disclose the use at least one surfactant chosen from anionic surfactants cationic surfactants nonionic surfactants and amphoteric surfactants (e.g., see Verdicchio et al., page 20, Examples X and XI showing the use of cocoamido betaine, amidohydroxypropyl phosphobetaine, polyoxyethylene (80) sorbitan laurate, polyethyelen glycol (150) distearate in lines 12-24. Finally, Verdicchio et al. also disclose a pH of "about" and wherein the composition has pH ranging from about to about 4.5 to 6.5 (e.g., see Verdicchio et al., page 20, line 25 showing pH = 6.6, which is "about" 6.5).

For ***claims 40 and 61***, Verdicchio et al. disclose at least one hydroxy pyridone of formula has cyclohexyl radical in the R^4 position (e.g., see Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, column 1, line 51).

For ***claims 41 and 62***, Verdicchio et al. disclose $CH_2CH(CH_3)CH_2C(CH_3)_3$ in the position in the R4 position (e.g., see Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, claim 3).

For ***claims 42 and 63***, Verdicchio et al. disclose Octopirox (i.e., 1-hydroxy-4-methyl-6-(2,4,4-trimethylpenty1)-2(H)pyridine (e.g., see Verdicchio et al., page 20, line 22; see also page 12, line 32 disclosing compounds set forth in U.S. Patent No. 4,185,106; see also Dittmar, claim 3).

For ***claims 48 and 64***, Verdicchio et al. method of treating seborrheic dermatitis in human patient in need thereof as claimed in claim 38 in which the composition further comprises at least one additional surfactant chosen from anionic cationic nonionic and amphoteric (e.g., see Verdicchio et al., page 20, wherein cocoamido betaine, amidohydroxypropyl phosphobetaine, polyoxyethylene (80) sorbitan laurate, polyethyelen glycol (150) distearate are disclosed; see also page 5, last paragraph, "The amphoteric surfactants which are useful in the compositions of the present invention include betaines … phosphobetaines").

For ***claims 65 and 66***, Verdicchio et al. disclose lactic acid to adjust the pH (Verdicchio et al., page 12, line 32 disclosing the use of compounds set forth in Dittmar i.e., U.S. Patent No. 4,185,106; see also Dittmar, column 5, line 47 disclosing the use of "lactic acid" salts).

In the alterative that dandruff is not considered to be the same thing as seborrheic dermatitis as argued by Appellants in direct contrast to the Janniger et al. reference, the claimed treatment would still be prima facie obvious to one of ordinary skill in the art because both dandruff and seborrheic dermatitis are produced by the same causative agent, Pityrosporum ovale, and is generally treated using the same types of medicinal shampoos (e.g., see Janniger et al., page 152, column 1 disclosing Piyrosporum ovale; see also column 2, Therapy section and Table 2). Thus, even if, for the sake of argument, dandruff could be

defined as a "separate" ailment apart from seborrheic dermatitis a person of skill in the art would still expect the same medicinal shampoos to be used in the treatment of both as defined by Janniger et al. Therefore, it would be prima facie obvious to treat the "separate" seborrheic dermatitis condition with a dandruff shampoo like the dandruff shampoo set forth in Verdicchio. One would have a reasonable expectation of success because both are conditions are produced from a common microbe, Pityrosporum ovale organism. In addition, Dittmar et al. explicitly state that their pyridones can be used as "anti-seborrheic agents." (e.g., see Dittmar et al., column 6, line 24). Thus, a person of skill in the art would be motivated to use the "dandruff" compositions to treat both seborrheic dermatitis as well as dandruff. Furthermore, a person of skill in the art would also have reasonably expected to be successful because all reference show the use of medicinal shampoos for the topical treatment of the scalp.

Double Patenting

Claims 38-42, 48 and 61-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23 and 26-29 of copending Application No. 10/606,229. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to the same treatment of seborrheic dermatitis using the same 1-

hydroxyl-2-pyridone compounds having the same generic formula. Thus the applications overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(10) Response to Argument

Claims Rejections - 35 U.S.C. 112, first paragraph

Argument 1:

Appellants argue, "The Presence of an Organic Acid as a pH Adjuster Does not Act as an Antiseborrheic Agent" (e.g., see Appeal Brief, section 2, starting on page 13).

Response 1:

In response to Appellant's argument that the references fail to show certain features of Appellant's invention, it is noted that the features upon which Appellant relies (i.e., "antiseborrheic" agent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 38, for example, reads, "a sole active component", it doesn't read, "a sole antiseborrheic component as erroneously implied. Thus, the claimed scope precludes any other active component regardless of the nature of the activity (i.e., it precludes antimicrobials as well in addition to antiseborrheic agents).

Argument 2:

Appellants argue, "The skilled artisan would know that given the level of acid dilution that would occur when one uses an acid to adjust pH, any alleged antimicrobial activity it might have would not survive such a dilution" (e.g., see Appeal Brief, pages 13 and 14, especially page 14, last paragraph).

Response 2:

Claim 38 reads, "a sole active component … ." It does not read, "a sole active component with minor amounts of other active ingredients … ." Thus, Appellants' arguments are not commensurate in scope with the claims. Appellants admit that that the claims require organic acids to make the salt form and Lange makes clear that these acids "per se possess anti microbial action." These facts are undisputed and consistent with case law. See *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963)) ("From the standpoint of patent law, a compound and all its properties are inseparable"). Thus, the aforementioned physiochemical properties cannot be "diluted" to zero as suggested. The fact that Appellants' specification does not mention this property is irrelevant because it would be an inherent feature of the molecule.

Argument 3:

Appellants argue, "Lange teaches that when the acid is mixed with a detergent-containing solution, any alleged antimycotic effect is destroyed. Based on Lange's

teaching that the surfactant composition (I) must be kept separate from the acid composition (II), one of ordinary skill in the art cannot conclude that an organic acid, when added to such a surfactant composition, would still retain its alleged antimycotic activity … Thus, the entirety of Lange does not show that organic acids, per se, have antimicrobial activity" (e.g., see Appeal Brief, page 15, especially last paragraph).

Response 3:

As correctly noted by Appellants in the "Legal Standard for Written Description" section starting on page 1, "The focus of the written description requirement lies in what the specification at issue teaches, not what extrinsic evidence, such as a scientific article or another patent, purportedly says with respect to its own disclosure." Here, it is respectfully submitted that Appellants have failed to apply their own test. Appellants' specification and claims do not require the mixing of the two stated shampoos in Lange (i.e., composition I and II) that allegedly destroys inherent physiochemical properties. Furthermore, even if it were proper, for the sake of argument, to look in this fashion at the Lange reference, the Lange reference does not teach, suggest or otherwise state anything about a diminution of "antimicrobial" properties. It only talks about antimycotic properties as noted in Response 1 above and thus Appellants arguments' are not commensurate in scope with the claims. Furthermore, Appellants have ignored the express teachings in Lange to the contrary (e.g., see Lange, page 7, "in using particular organic acids … which acids per se possess an anti-microbial action … In this way the

effect of the antimycotic … is enhanced"). Appellants' position is also inconsistent with applicable case law holding, "a compound and all its properties are inseparable [i.e., can't be destroyed]." See *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Argument 4:

Appellants argue, "the Examiner concludes that the claims preclude the use of all other active components whether they are useful in treating SD or not … The Examiner's interpretation of claim 38 improperly considers this claim in a vacuum … claim 38 itself indicates that the 'active component' is active against SD … The preamble of claim 38 clearly connects the treatment of SD with the composition administered to the patient. The sole 'active' ingredient in this composition to treat SD is an ingredient that is active against SD" (e.g., see Appeal Brief, pages 15 and 16, especially page 16, second to last paragraph).

Response 4:

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Genus*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As noted in Response 1, Claim 38 reads, "a sole active component"; it doesn't read, "a sole active antiseborrheic component" as erroneously implied. Thus, Appellants' arguments are not commensurate in scope with the claims. Furthermore, Lange teaches that the antimicrobial organic acids also produce a

favorable antisebborrheic effect and thus possess both properties (e.g., see Lange et al., page 7, last paragraph, "using particular organic acids … acids per se possess an anti microbial action … In this way the effect of the antimycotic in phase I as well as phase II is enhanced"). Thus, even if, *assuming arguendo*, the claims could be interpreted as purported by Appellants, the result would not change.

Claims Rejections - 35 U.S.C. 112, second paragraph

Argument 1:

Appellants argue, "Lange shows that an organic acid loses it antimycotic activity when mixed with a detergent. Thus, the organic acid, even if it were present in the composition of claims 28 and 39, would not be an active ingredient against SD" (e.g., see Appeal Brief, pages 17 and 18, especially page 18, paragraph 1).

Response 1:

As noted above, "a compound and all its properties are inseparable." See *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963). Thus, the organic acid cannot "lose" its inherent, physiochemical properties. Furthermore, even if, for the sake of argument, the properties could somehow be separated from the molecule, the properties to which Appellants refers (i.e., "antimycotic") are not the properties at issue ("i.e., antimicrobial"). In addition, even if, *assuming arguendo*, Lange taught that the "antimicrobial" properties were somehow destroyed by the detergents in Lange, it only

would speak to the detergents disclosed in that reference, not the currently claimed genus of all anionic, cationic, nonionic and amphoteric surfactants/detergents as set forth, for example, in claim 38. Thus, Appellants' arguments are not commensurate in scope with the claims. Please see Response 1-4 in the 35 U.S.C. § 112, first paragraph rejection for a more detailed explanation on these points.

Argument 2:

Appellants argue, "When interpreting the meaning of a term in a claim, the Examiner should turn to the specification … The Examiner noted [previously in prosecution] … Appellants' specification never mentions this important 'hallmark' [i.e., hyperproliferation of keratinocytes] … that distinguishes seborrheic dermatitis from dandruff … Appellants respectfully remind the Examiner that the inventor may describe the invention in any way he sees fit … The declarations that Appellants submitted [i.e., Plott, Leaden, & Wortzman Declarations] were for the Examiner's benefit, to educate him on that knowledge" Appellants further note, as before with regard to the Dascalu reference, that Dascalu does not mention the 'hyperproliferation of keratinocytes' that is the hallmark of SD (as noted by Dr. Leaden), nor does Dascalu teach 'oily, yellowish scales," which result from this condition" ((e.g., see Appeal Brief, pages 19-21; see also Declarations themselves for various interpretations on what constitutes seborrheic dermatitis).

Response 2:

These statements, if not internally inconsistent, only serve to reinforce the Examiner's point that the term seborrheic dermatitis is unclear and that the specification does provide the requisite guidance to fix the problem. For example, Appellants state, "When interpreting the meaning of a term [i.e., seborrheic dermatitis] in a claim, the Examiner should turn to the specification." However, when the Examiner did just that and asked where in the specification is the alleged hallmark feature that distinguishes seborrheic dermatitis from dandruff (i.e., hyperproliferation of keratinocytes), Appellants stated that it's not there because their "inventor may describe the invention any way he sees fit." How then can the Examiner determine the true meaning of seborrheic dermatitis from the specification as purported when such essential ingredients are missing from the alleged definition? Presumably, the missing "education" must come from Appellants' declarations, the prosecution history, and the art. As noted in the advisory (e.g., see pages 6-10), the term seborrheic dermatitis has a highly disputed meaning in the art and has not been used consistently by Appellants in the prosecution history. Furthermore, Appellants' declarations do not refute any of these points. For example, as noted previously (see 7/16/07 Advisory, page 9, paragraph 1), "hyperproliferation of keratinocytes" could not possibly be the "hallmark" that separates seborrheic dermatitis from dandruff when dandruff also involves such hyperproliferation (e.g., see Sanfilippo et al., "An Overview of Medicated Shampoos Used in Dandruff Treatment" P7T 2006, 31(7), pages 396-400, especially page 396, column 2, paragraph

3, "The pathogenesis of dandruff involves hyperproliferation"). Likewise, Appellants' reference to yellowish scales as a possible means for distinguishing seborrheic dermatitis also fails in view of the previously submitted International Eczeme-Psoriasis Foundation paper stating on page 1, paragraph 1, "Seborrheic dermatitis, also known as Dandruff [i.e., both dandruff and seborrheic dermatitis display the same symptoms] … is … characterized by loose, greasy or dry, white to yellowish scales").

Furthermore, Appellants stated previously in the prosecution history, "Dascalu et al. misuses dermatology nomenclature by confusing 'dandruff' with 'seborrheic dermatitis' … Although seborrheic dermatitis involving the scalp may give rise to a mistaken diagnosis of dandruff, it is well understood in the field of dermatology that seborrheic dermatitis is a condition distinct from dandruff" (e.g., see 4/24/02 response, pages 19-20). Appellants define "seborrheic dermatitis" as "a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites" (e.g., see specification, page 1). Appellants further state, "Pityrosporum … is assumed to be the cause of seborrheic dermatitis" (e.g., see specification, page 1, last paragraph). However, Dascalu et al. disclose a treatment for the exact same symptoms as those defined in Appellants' specification (e.g., see Dascalu et al., line 12 wherein inflammation is disclosed; see also page 5, Table 1, patient 5, wherein a high degree of scaling is disclosed; see also page 5, Table 1, patient 2 wherein a high degree of "itching" is

disclosed; see also Table 5, patient 5 wherein the overall severity of the dandruff is characterized as "severe" or, in Appellants' words, not just "simple dandruff"). In addition, Dascalu et al. explicitly state that their treatment inhibits the exact yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Appellants are relying on to make this distinction (i.e., there is no basis for this assertion). Thus, Appellants' have not consistently used the term SD throughout the prosecution history.

Finally, as noted in the 2/25/07 Final Office action, the term is also disputed in the art. For example, Janniger et al. states, "Seborrheic dermatitis is a common condition that usually appears as simple dandruff" (e.g., see Janniger et al., page 149, column 1, paragraph 1; see also abstract). This position was further reinforced in the 7/16/07 Advisory (see page 9, paragraph 1) by the International Eczeme-Psoriasis Foundation and WebMD papers (e.g., see page 1, paragraph 1, "Seborrheic dermatitis, also known as Dandruff [i.e., Seborrheic dermatitis is Dandruff]"; see also WebMD paper, page 1, "Sebborea is also known as seborrheic dermatitis or common dandruff").

Claims Rejections - 35 U.S.C. 102 (Lagarde)

Argument 1:

Appellants argue, "Lagarde does not teach or even remotely suggest non-combination products, i.e., a 'single' composition comprising a "sole" active component, or the use of 1-hydroxyl-2-yridones as a sole active component. Instead, Lagarde is entirely focused on the synergism resulting from the combination of his two active ingredients i.e., the treatment of "skin fungal infections" with a compositions comprising two separate components – 1 hdyroxy-2-pyridone and crotamiton" (e.g., see 12/21/07 Appeal Brief, pages 21-23, especially page 23, paragraph 1).

Response 1:

As noted previously (e.g., see 7/16/07 Advisory, page 13, paragraph 1), Appellants' claims encompass more than just one active ingredient (e.g., see 35 U.S.C. § 112, second paragraph rejection above) and, as a result, Appellants' argument is moot. Furthermore, the term synergism is defined as two or more agents acting together to create an effect greater than that predicted by adding the effects of the individual agents. Thus, the term synergism as used in Lange necessarily teaches that each individual agent would create at least some effect when used alone.

Claims Rejections - 35 U.S.C. 102 (Lange)

Argument 1:

Appellants argue, "Despite the fact that the Board vacated a rejection that used Lange as the central reference and noted, in its previous opinion in this case, that Lange was not the closes prior art, the Examiner continues to use Lange as a basis for anticipation" (e.g., see 12/21/07 Response, paragraph bridging pages 24 and 25).

Response 1:

The Examiner agrees that Lange is being used again here in the anticipation analysis. However, the Examiner consulted his SPE, a QAS and the Director of the TC and further obtained both the SPE's and Group Director's signature on the 1/17/06 Office Action before mailing. Thus, the case has not been improperly treated on the merits as suggested. In addition, the present Examiner did not write the Final Office action previously on Appeal and new facts/issues were raised in the 1/17/06 non-final Office action that were not brought to the Board's attention on the first Appeal. Further, Appellants amended the claims in response to the 1/17/06 Non-final Office Action in an attempt to overcome both Lagarde and Lange (e.g., see 7/17/06 Response, page 10, "First rejection under 35 U.S.C. § 102", "The method of independent claim 39 has now been amended to recite administering a composition comprising a sole active component … ."; see also paragraph bridging pages 11 and 12, "They [Lange] are two separate products or compositions, unlike the [currently] claimed invention which is a

single composition; see also 7/17/06 claim set wherein this "single" composition limitation was added), which strongly suggests that Appellants agreed with the propriety of the rejection (i.e., otherwise they would not have amended the claims in their 7/17/06 response to the 1/17/06 non-final office action).

Argument 2:

Appellants argue, "Lange teaches a product made of two separate compositions or phases … Lange clearly teaches that combining phase I and phase II into a single composition is 'not feasible.' Lange at 4. Lange teaches that the two phases should not be packed together because "both compositions may not be mixed without loss of effectivity." Lange at 11. Clear, Lange does not teach a single composition as recited in rejected claim 39" (e.g., see Appeal Brief, page 24, middle paragraph).

Response 2:

As noted previously (see 7/16/07 Advisory, page 16, last paragraph), Appellants' specification does not teach that a "single" application of a composition will "permanently" cure seborrheic dermatitis. Rather, multiple applications of the same composition over time are taught (e.g., see specification, Example 8 wherein the "single" composition is reapplied throughout the week). Thus, the claimed limitation of treating seborrheic dermatitis with a "single composition" must not be construed to preclude the application of more than one composition later in time. That is, a person of skill in the art would not reasonably construe the claims to read on a "single application"

of a "single composition" but, rather, "multiple applications" of the "single composition" over a period of time. Further, Appellants use of "comprising" open-ended terminology (e.g., see claim 38, "A method of treating seborrheic dermatitis … comprising") does not preclude the use of "additional" ingredient later in time. Here, Lange discloses the use of piroctone olamine and sodium laurel sulphate in a "single" phase I composition (e.g., see above rejection). The fact that another "different" composition is used "later in time" is the immaterial because it does not negate the fact that a "single" composition was first applied consistent with the teachings in the specification as noted above. Therefore, the phrase, "administering to the patient … a single composition" has been interpreted to mean a single composition administered at a give time, not a single composition administered for all times. Thus, Lange's phase I composition anticipates the claimed invention because it constitutes a "single" composition within the meaning of Appellants' claims. Consequently, the Examiner has not dismissed Appellants' claimed limitation but, rather, chosen to give this limitation its broadest reasonable interpretation consistent with the specification. See MPEP § 2111.

Argument 3:

Appellants argue, "the issue is not whether the same single composition is applied multiple times over a period of time for treatment, but instead whether, each time the treatment is administered, multiple compositions have to be applied at a single sitting … the present claims require application of one composition for treatment, not

two or more" (e.g., see 12/21/07 Appeal Brief, pages 25 and 26, especially paragraph bridging pages 25 and 26).

Response 3:

In response to Appellant's argument that the references fail to show certain features of Appellant's invention, it is noted that the features upon which Appellant relies (i.e., "each time" a single composition is employed in a "single sitting") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, Appellants' open-ended "comprising" terminology would not preclude the use of additional ingredients in subsequent applications.

Argument 4:

Appellants argue, "even if one were to try and make a single composition from the two separate phases taught in Lange, the skilled artisan would have to pick and choose specific elements from Lange to arrive at the claimed single composition. Such picking and choosing, without guidance in the reference as to which elements should be combined, is not a proper foundation for anticipation" (e.g., see 12/21/07 Appeal Brief, page 26, middle paragraph).

Response 4:

No such "picking and choosing" is required. As noted in the above rejection, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using a "single" phase I composition that contains all the claimed ingredients (e.g., see page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant … In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset), chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"; see also Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the ***sole*** anti-mycotic"). Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same phase I composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant … which is included as a foaming agent … in a huge variety of commonly used products … shampoos"). Thus, everything is contained in one composition and no "picking and choosing" is required.

Claim Rejections - 35 USC § 103 (Lange)

Argument 1:

Appellants argue, "the Examiner has not offered any support to show that the skilled artisan would have 'reasonably expected to have been able to' use anionic surfactants, cationic surfactants, nonionic surfactants and amphoteric surfactants in an acidic composition. Thus, Lange … expressly teaches away from the claimed invention … one of ordinary skill in the art would have learned from Lange that a composition containing detergents or surfactants cannot be mixed with an acidic composition to yield a product that is effective for treating SD" (e.g., see 12/21/07 Appeal Brief, especially paragraph bridging pages 30 and 31).

Response 1:

In response to Appellant's argument that the references fail to show certain features of Appellant's invention, it is noted that the features upon which Appellant relies (i.e., "acidic" composition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As noted in the rejection above, a pH range between 6-8 is considered to be "neutral", not "acidic" as exemplified by Dreumex, Odds et al. and Brinkster (e.g., see Dreumex, page 1, "Dreumex has developed three types of liquid soaps: Each has a (netural pH-value of 6-7; see also Odds et al., column 5, last paragraph, "Some of the first active ingredients when at approximately neutral pH (pH 6 to 8)"; see also Brinkster,

"Solutions with a pH between 6 and 8 are usually referred to as 'neutral' by nonscientists"). Thus, Appellants' claimed ph range from about 4.5 to about 6.5 encompasses both "acidic" and "neutral" embodiments. In addition, the term "about" likely pushes this range up to pH 7.0 itself.

With regard to Appellants' "teaching away" argument, the test is whether is one "would be discouraged from following the path set out in the reference, or would be lead in a direction divergent from the path that was taken by the Appellant" *In re Gurley*, 27 F.3d at 553, 31 USPQ2d at 1131 (Fed. Cir. 1994). Here, Lange teaches a "neutral" pH, which according to the art (i.e., Dreumex, Odds et al., and Brinkster), would constitute a values between 6 and 8). Thus, a person would not have been "deterred" from using the claimed values of 6.0 to about 6.5 because these values are specifically taught by Lange et al. (when considering the teachings of Dreumex, Odds et al., and Brinkster). Further, overlapping ranges do not represent a "teaching away" but, rather, a *prima facie* case of obviousness according to the courts. See MEPE 2144.05, "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a prima facie case of obviousness exists.'" Further, Lange teaches a pH range of 4-6 can be used in the "phase II" solution (e.g., see page 10, paragraph 2), which indicates that piroctone olamine (which can be used in both "phase I" and "phase II" composition) would still continue to function as an anti-mycotic even at a lower "acidic" (i.e., less than pH 6.) range. In addition, a person of ordinary skill in the art would be motivated to use

a lower pH range because of its favorable bacterio and mycostatic properties (e.g., see Lange, page 15, bottom of page).

Argument 2:

Appellants argue, "One of ordinary skill in the art would not have applied Dascalu to the claimed invention, because Dascalu teaches compositions containing two active ingredients, a cytotoxic agent and an antifungal agent for treating dandruff, which is a different condition from SD" (e.g., see 12/21/07 Appeal Brief, page 31, first full paragraph).

Response 2:

The Examiner respectfully disagrees. Dascalu et al. expressly state that ciclopiroxolamine is useful for treating seborrheic dermatitis (e.g., see claims 1 and 4, "A composition for treatment of seborrheic dermatitis of the scalp … consisting of … ciclopiroxolamines"). It is submitted that the mere substitution of one component for another to yield predictable results represents a *prima facie* case of obviousness. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (U.S. 2007). In this case, Dascalu et al. indicates that this compound, ciclopiroxolamine, would be useful for treating the same disease seborrheic dermatitis. Further, even if, *assuming arguendo*, Dascalu only taught dandruff instead of SD, the causative agent and symptoms are so similar (almost identical) that a person of ordinary skill in the art would immediately recognize that you could use the same agent to treat both.

Argument 3:

Appellants argue, "Green People and Avvre provide generic background information on certain chemical agents … [and thus] have no link to a method of treating SD or to the single composition described in claims 38 and 39. Brinkster and Dreumex [likewise] appear to provide general background information on the pH scale … Odds, like Legarde and Lange, teaches a combination product, emphasizing the importance using both components together … [thus] a method of treating SD using a single composition [is not taught]" (e.g., see 12/21/07 Appeal Brief, pages 31 and 32).

Response 3:

It is respectfully submitted that this "single composition" argument has been adequately addressed in the rejection above, the Lange Response under 35 U.S.C. § 102 and Lagarde et al. response by analogy. It has never been the Examiner's position that these "generic" teachings with regard to pH scale, etc. provide this claim limitation.

Argument 4:

Appellants argue, "Mr. Kevin Kriel [attested] to the commercial success of compositions comprising 1-hydroxyl-2-pyridone with the claim limitations, using Loprox Shampoo … [noting] advertising alone would not speak to the repeat sales described in Mr. Kriel's declaration … if the product is not of good quality and effect, they will not buy more of the product … [further] Loprox Shampoo is merely an example of these

compositions. Thus, Mr. Kriel's declaration provide information on commercial success that is commensurate in scope with the claims on appeal" (e.g., see 12/21/07 Appeal Brief, pages 32 and 33).

Response 4:

The Kriel declaration doesn't mention anything about "repeat" sales. Further, as noted previously, Loprox is not commensurate in scope with the claims. For example, Mr. Kriel does not indicate which of the currently claimed surfactants is used in Loprox (i.e., anionic, cationic, amphoteric, non-ionic, amphoteric, etc.) so it's not even clear if a claimed surfactant is being used. Furthermore, Mr. Kriel never states that Loprox falls within the scope of the current claims but, rather, relies on a third party (i.e., the legal counsel of Loprox) for this assertion (see paragraph 1, "According to legal counsel, Loprox Shampoo is … covered by claims 38, 39, 40, 42, 48, 61, 63 and 64"), which was not made under oath/affirmation. Furthermore, Kevin Kriel states that ciclopirox, not all of the currently claimed 1-hydroxyl-2-pyridones of formula I, has allegedly produced the increase sales (e.g., see Kriel Declaration, point 3, "No other ciclopirox shampoo is currently marked in the U.S. to date."). Thus, the declaration at best only provides support for ciclopirox (i.e., the active ingredient in the Loprox shampoo), not the currently claimed genus of 1-hydroxyl-2-pyridones. In view of the foregoing, when all of the evidence is weighed again use all of the available secondary evidence, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claims Rejections – 35 U.S.C. 102/103 (Verdicchio et al.)

Argument 1:

Appellants argue, "Verdicchio does not teach a method of treating SD. Rather, Verdicchio consistently discusses treating dandruff, which is a separate conditions from SD … The Examiner's reliance on Janniger is misplaced, because Janniger improperly confuses the term 'dandruff' with the term 'seborrheic dermatitis.' … [furthermore the] use of Janniger is yet another example of how the Examiner chooses to override the specification's teachings" (see 12/21/07 Appeal, pages 33 and 34, especially page 34, last paragraph).

Response 1:

As noted previously (e.g., see 7/16/07 Advisory, page 30), the term seborrheic dermatitis is unclear and the specification does not fix this problem (e.g., see 35 U.S.C. § 112, second paragraph rejection above and corresponding arguments/responses; see especially response 2 noting that "essential" ingredients like the alleged "hallmark" between dandruff and SD is not set forth in the specification). Furthermore, as noted in the 7/16/07 Advisory, Janniger was not the only one to allegedly "confuse" the definition. The WebMD reference, for example, recites, "Seborrhea is also known as seborrheic dermatitis or common dandruff" and the symptoms and causative agent disclosed by Verdicchio, Lange, etc. are not inconsistent with the "definition" set forth in Appellants'

specification (e.g., see paragraph 1) and the ambiguous prosecution history (e.g., see above discussion with regard to the Dascalu reference). Further, even if, *assuming arguendo*, the boundaries between SD and dandruff could somehow be clearly delineated within the meaning of 35 U.S.C. § 112, second paragraph, the causative agent and symptoms are so similar (e.g., 4/24/02 response, pages 19-20 wherein Appellants admit that one is commonly misdiagnosed for the other), that a person of ordinary skill in the art would immediately recognize that one therapeutic agent could be used to treat both diseases.

Argument 2:

Appellants argue, "the Federal Circuit has held that similar language [as that recited in Appellants' preamble] distinguishes the treatment of a disease from the treatment of mere symptoms of that disease … the preambles of the claims of Jansen, Rapoport, and present application ought to be interpreted to exclude prior art that fails to reveal any intent to treat the underlying conditions just like the preambles in Jansen and Rapoport" and cited *Jansen v. Rexall Sundown*, Inc. in support of this position (e.g., see 12/21/07 Appeal, pages 35 and 36).

Response 2:

The causative agent for both SD and dandruff (assuming they are different) is the same (i.e., the yeast Pityrosporum). Thus, the art does not "fail to reveal any intent to treat the underlying conditions" because the underlying conditions (i.e., Pityrosporum)

are the same. Further, the symptoms are virtually identical and often misdiagnosed (one for the other) as noted above. Further, cases like *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) ("BMS") seem to support an opposite conclusion since they contain similar language (e.g., claim 1, "A method for reducing hematologic toxicity in a cancer patient undergoing taxol treatment comprising parenterally administering to said patient an antineoplastically effective amount of about 135-175 mg/m2 taxol over a period of about three hours.") that was held to be mere "intended use" rather than a patentable limitation. That is, there seems to be little difference between "the human in need thereof" phrase from Jansen and "a cancer patient undergoing taxol treatment [i.e., presumably only humans in need thereof undergo such a treatment]" in *BMS*.

Argument 3:

Appellants argue, "the foundation for this obviousness rejection is the perception that dandruff and SD are caused by the same organism. But, as Appellant has explained, at the time of the invention, it was unclear to person of ordinary skill in the pertinent art as to what causes SD … [noting] Lange … [and] Dr. Wortzman … [provide] contrary teachings that do not suggest that *P. ovale* is the cause [for both dandruff and SD] (e.g., see 12/21/07 Appeal, pages 37 and 38, especially page 38, paragraph 2).

Response 3:

As noted prior (e.g., see 7/16/07 Advisory Action, page 30, last paragraph), Obviousness does not require "absolute" predictability. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Clinton, 527 F.2d 1226, 188 USPQ 365 (CCPA 1976). Thus, the fact that there may have been conflicting view (i.e., Lange/Wortzman declaration) on what causes SD/dandruff is not dispositive. The fact remains that many believed that SD and dandruff were both caused by the same agent, *P. ovale*, and the symptoms were so close that, according to Appellants' own admission, the two allegedly distinct diseases were commonly misdiagnosed one for the other (see above). Thus, a "reasonable" expectation exists here that a single therapeutic agent could be used to treat both. Furthermore, people in the art commonly used the same medication to treat both conditions (e.g., see Janniger et al., page 152, column 1, disclosing *P. ovale*; see also column 2, Therapy section and Table 2; see also Lange, "page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant" showing again the state of the art was such that anti-mycotics were used for both).

Argument 4:

Appellants argue that a "teaching away" still exists with regard to the Dittmar reference and that SD and dandruff are so different that one would not possible use the same therapeutic agent to treat both (e.g., see 12/21/07 Appeal, pages 39 and 40).

Argument 4:

As noted previously, no such teaching away exists. The test to determine if a reference "teaches away" is to determine if one "would be discouraged from following the path set out in the reference, or would be lead in a direction divergent from the path that was taken by the Appellant" *In re Gurley*, 27 F.3d at 553, 31 USPQ2d at 1131 (Fed. Cir. 1994). For example, in *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988), a system for measuring minute quantities of nitrogen presumably for the detection of drugs and explosives was claimed. The claims were rejected as being obvious over Eads in view Warnick. Eads disclosed a method for separating and identifying sulfur compounds. Warnick disclosed a process for detecting pollutants in the atmosphere by measuring the level of nitric oxide. The PTO held that it would have been *prima facie* obvious to substitute the nitric oxide detector of Warnick for the sulfur dioxide detector of Eads. On appeal, the Federal Circuit reversed noting that Eads deliberately sought to avoid the use of nitrogen because the sulfur detector was adversely affected by substantial quantities of nitrogen. Thus, according to the CAFC, "instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention." See *Id.* at 1599. Thus, *In re Fine* provides an example of a "teaching away" by disclosing that the presence of a claimed element, nitrogen, is undesirable. No such "teaching away" exists in the present case. That is, neither Dittmar nor Verdicchio teach that the claimed method of treatment "will not work" unless multiple active ingredients are used. To the contrary, Verdicchio

expressly states that multiple active ingredients are not required. Further, as noted at length above, these are not completely different diseases. To the contrary, the record indicates that they are commonly "misdiagnosed" one for the other, the art recognizes them as being the same disease, they are believe to possess (by many) the same symptoms/causative agents, etc. Thus, a person of skill in the art would reasonably believe that the same therapeutic agent could be used to treat both. Finally, it should also be noted that Appellants' "teaching away" is not applicable to the "102" rejection noted above (i.e., teaching away arguments are only applicable to 103 rejections).

Double Patenting

Argument 1:

Appellants argue, "Because this rejection is provisional … Appellants have not yet filed a Terminal Disclaimer … If, however, patentable subject matter is identified … Appellants will file a Terminal Disclaimer" (e.g., see 12/21/07 Appeal Brief, page 40, especially last paragraph).

Response 1:

Appellants seem to be asking that the rejection should be held in abeyance because it is a "provisional" rejection. However, MPEP §804 B reads, "The 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless

that "provisional" double patenting rejection is the only rejection remaining in one of the applications."). Here, a double patenting rejection is NOT the only rejection remaining in one of the applications and thus the double patenting rejection is proper especially since Appellants have not questioned the merits of the rejection.

(11) Related Proceeding(s) Appendix

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal: Previously decided Appeal No. 2004-0309 and ongoing appeal for related application 10/606,229 (appeal number has not yet been assigned).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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